UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: October 6, 2021

SUBJECT: Efficacy Review for Virocid,
EPA Reg. No. 71355-1
Action Code Case #: 00304297; E-sub: 64097

FROM: M. Jason Duncan
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Date Signed: October 13, 2021

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Date Signed: October 13, 2021

THRU: Kristen Willis, Chief
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Date Signed: October 12, 2021

TO: Eric Miederhoff, PM 31 / Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: CID LINES N.V.
Authorized Agent: Ecolab Inc.

Formulation from the Label:

Active Ingredient(s)	% by wt.
Alkyl Dimethyl Benzyl Ammonium Chloride (50% C14; 40% C12; 10% C16)	17.060%
Didecyl Dimethyl Ammonium Chloride	7.800%
Glutaraldehyde	10.725%
Other Ingredients	64.415%
Total	100.000%

I BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid (Dilutable)

Submission type: Label Amendment

Currently registered efficacy claim(s): Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment

Requested action(s): Add disinfection claims against additional viral pathogens for non-porous and porous surfaces.

Documents considered in this review:

- Cover letter from applicant to EPA dated 5/25/2021
- Proposed label dated 5/21/2021
- Data Matrix (EPA Form 8570-35) dated 5/25/2021
- Two studies (MRIDs 51549301 and 51549302)
- Confidential Statement of Formula – Basic, dated 09/28/10
- Rationale for ASFV dilution
- Certificate of Analysis for ASFV study, dated 01/15/2019.

II PROPOSED DIRECTIONS FOR USE

"**Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:**

1. **Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):**
   For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, aluminum sandwich panels and feeding/drinking equipment:
   A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
   B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the appropriate disinfection solution by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
   C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
   D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
   E. Disinfection of equipment: Immerse all previously cleaned halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution for 10 minutes. Allow to air dry.
   F. Fresh disinfection solution should be made daily or if visibly soiled.

2. Hatcheries:
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution must be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. Trucks and other vehicles:
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

VIRUS (on environmental surfaces)	DILUTION
SARS-Related Coronovirus 2 [SARS-CoV-2] [USA-WA1/2020][BEI NR-52281]**	1:400
African Swine Fever Virus****	1:256

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III STUDY SUMMARIES

1.	**MRID**	51549301		
Study Objective		Disinfectant -- virucidal		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest; A32213		
Experimental Start Date		02/26/2021	**Study Completion Date:**	05/24/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		SARS-Related Coronavirus 2, BEI Resources NR-52281, Strain Isolate USA-WA1/2020		
Indicator Cell Culture		Vero E6 cells (ATCC CRL-1586)		
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces (ASTM E1053-20)		
Application Method		Diluted Liquid		
Test Substance Preparation	**Name/ID**	Virocid		
	Lots **☐ 1 ☐ 2 ☒ 3**	3512042885, 3512042886, 3512042887		
	Preparation	Tested concentration: LCL Tested Dilution: 1:409 (for batches 3512042885 and 3512042886; 1:416 for batch 3512042887) Diluent: 400 ppm AOAC synthetic hard water		
Soil load		5% FBS		
Carrier type, # per lot		Glass petri dish, 1 carrier per lot		
Test conditions		Contact time: 1 minute		

	Temperature: 19.43°C Relative humidity: 20.10%
Neutralizer	Sephadex Gel Filtration Columns
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	N/A

2.	**MRID**	51549302		
Study Objective		Disinfectant -- virucidal		
Testing Lab; Lab Study ID		Plum Island Animal Disease Center		
Experimental Start Date		10/10/2019	**Study Completion Date:**	1/4/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		African Swine Fever Virus strain BA71V1		
Indicator Cell Culture		Vero cells		
Test Method		Quantitative Method for Evaluating Virucidal Activity of Microbicides used on Hard Non-Porous Surfaces.		
Application Method		Dilutable Liquid		
Test Substance Preparation	**Name/ID**	Virocid		
	Lots **☒ 1 ☐ 2 ☐ 3**	0081929186		
	Preparation	Tested concentration: Nominal Tested Dilution: 1:256 Diluent: 375 ppm hard water		
Soil load		3-part soil load (23% v/v solution of 0.35% yeast extract, 0.25% BSA, and 0.08% bovine mucin)		
Carrier type, # per lot		AISI 430 stainless steel coupons, concrete coupons [fine cementitious material from Sakrete High-Strength Concrete Mix (Lowes, 132022)], 7 carriers per lot		
Test conditions		Contact time: 10 minutes Temperature: 22±2°C Relative humidity: N/A		
Neutralizer		10 mL Complete Dulbecco's Modified Eagle Medium (cDMEM) + 2% fetal bovine serum (FBS)		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A		

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot No. 3512042885	Lot No. 3512042886	Lot No. 3512042887	
1 min contact time, 1:409-416 of 400 ppm AOAC Hard Water, 5% fetal bovine soil						
51549301	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-Related Coronavirus 2), Strain: USA-WA1/2020; BEI Resources NR-52281	10^{-1} to 10^{-6} dilution*	Complete inactivation	Complete inactivation	Complete inactivation	5.05
		Log_{10} $TCID_{50}$/ carrier	≤ 0.80	≤ 0.80	≤ 0.80	
		Log_{10} Reduction	≥ 4.25	≥ 4.25	≥ 4.25	

MRID	Organism	Description	Results			
			Lot 0081929186 (Steel Carriers)		Lot 0081929186 (Concrete Carriers)	
10 minutes, 1:256 dilution, 3-part soil load						
		Replicate	*1*	*2*	*1**	*2**
51549302	African Swine Fever Virus strain BA71V1	10^0 dilution	T	T	T	A: 6+/6 B: 2+/6 C: 3+/6 D: 4+/6 E: 0+/6 F: 5+/6 G: 3+/6
		10^{-1} dilution	Complete inactivation	Complete inactivation	A: 0+/6 B: 1+/6 C: 0+/6 D: 0+/6 E: 1+/6 F: 0+/6 G: 0+/6	A: 3+/6 B: 2+/6 C: 0+/6 D: 1+/6 E: 0+/6 F: 3+/6 G: 4+/6
		10^{-2} dilution	Complete inactivation	Complete inactivation	Complete inactivation	A: 0+/6 B: 0+/6 C: 0+/6 D: 0+/6 E: 0+/6 F: 2+/6 G: 2+/6
		10^{-3} dilution	Complete inactivation	Complete inactivation	Complete inactivation	A: 1+/6 B: 0+/6 C: 0+/6 D: 0+/6 E: 0+/6 F: 0+/6 G: 0+/6
		10^{-4} dilution	Complete inactivation	Complete inactivation	Complete inactivation	A: 0+/6 B: 0+/6 C: 0+/6 D: 0+/6 E: 0+/6 F: 1+/6 G: 0+/6
		10^{-5} to 10^{-7} dilution	Complete inactivation	Complete inactivation	Complete inactivation	Complete inactivation
		Log_{10} $TCID_{50}$/carrier	<1.3	<1.3	<1.3	1.9
		Log Reduction	5.2	4.4	4.0	4.2
		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)	6.5	5.7	5.3	6.1

T = cytotoxic

*X+/Y = number of positive wells out of 6 total wells inoculated.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51549301	Disinfectant, virucidal	Hard non-porous surfaces	Liquid at 1:400 dilution	1 minute	5% FBS	400 ppm hard water	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-Related Coronavirus 2), Strain: USA-WA1/2020; BEI Resources NR-52281	**Yes**
51549302	Disinfectant, virucidal	Hard porous and non-porous surfaces	Liquid at 1:256 dilution	10 minutes	3-part soil (23% v/v solution of 0.35% yeast extract, 0.25% BSA, and 0.08% bovine mucin)	375 ppm hard water	African Swine Fever Virus strain BA71V1	**Yes –** however, testing was conducted at the nominal dilution. Label dilution should be adjusted to reflect LCL.

VI LABEL COMMENTS

Label Date: 05/21/2021

1. The proposed label claims that the product, Virocid, when diluted at 1/3 fl. oz. per gallon of water, is an effective disinfectant against the following on visibly clean hard, non-porous surfaces for a 1-minute contact time:

   Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-Related Coronavirus 2), Strain: USA-WA1/2020; BEI Resources NR-52281

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Virocid, when diluted at 1/2 oz. per gallon of water, is an effective disinfectant against the following on visibly clean hard, porous and non-porous surfaces for a 10-minute contact time:

   African Swine Fever Virus

   These claims are **partially acceptable**. As per the proposed rationale for ASFV dilution and prior discussion between EPA and Ecolab, to account for conducting testing using one batch at nominal instead of the LCL, the label dilution should be adjusted to ensure efficacy for end users to a minimum of 1:240 dilution. For simplicity, we recommend that the label dilution be revised to 1:200, equivalent to existing dilution preparation instructions for Porcine circovirus, type II. Otherwise, appropriate dilution preparation directions should be provided in the table on page 3.

3. On page 3 of the label,
   a. Under each set of disinfection use directions, specify that surfaces should remain "visibly wet" for the duration of the contact time
   b. under "Hatcheries" and "Trucks and other vehicles" specify "hard non-porous surfaces"

4. On page 7 of the label,
   a. specify "on hard nonporous surfaces" for SARS-CoV-2 claim.
   b. revise "This product {or marketed product name} is effective against the following animal pathogen on porous and hard non-porous inanimate surfaces" to "This product {or marketed product name} is effective against the following animal pathogen on hard porous and hard non-porous inanimate surfaces."